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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/923,752 | 08/07/2001 | Maneesh Jain | 2002850-0015 | 3181 |

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| EXAMINER | |
|---|---|
| DO, PENSEE T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/923,752 | JAIN ET AL. | |
| | Examiner | Art Unit | |
| | Pensee T. Do | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-112* is/are pending in the application.

4a) Of the above claim(s) *69-112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-112* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of group I, claims 1-68, in the reply filed on February 16, 2005 is acknowledged. The traversal is on the ground(s) that the process as claimed in group III, claims 74-77, requires the use of the device of group I; and the method of group IV and the method of group I are capable of use together. This is not found persuasive because the device can be practiced in a different process such as a process of separating magnetic particles-bound to target analytes from a sample mixture. Regardless of what the device of group I is used for, it is just a substrate comprising of magnetic regions. Thus, such as substrate can be used in different process. Regarding the argument between group I and IV, the two groups are not capable of use together even though the claims in group IV requires the device of group I. The device is just a substrate with magnetic regions. Forming an array of magnetic particles does not necessary require the device of group I. An array of magnetic particles may form by attaching the magnetic particles to one side of a substrate (without the magnetic regions) and applying a pattern of magnetic field on the other side of the substrate to manipulate the magnetic particles to form an array according to the pattern of the magnetic field.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Objections*

Claims 7-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 4. See MPEP § 608.01(n). Accordingly, the claims 7-9 not been further treated on the merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it fails to further limit claim 1. The recitation of "at least 3 times greater..." is broader than "at least 5 times greater.." in claim 1.

Claims 42-44 are vague. It is unclear as to how the components, i.e. a flux circulator, a plurality of photodetectors, and a microfluidic assembly, are related to the components of the device in claim 1.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 12, 14, 15, 21-23, 26-30, 32, 35-36, 38-41, 59, 61-63, 65-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Baglin et al.(US 6,440,520).

Baglin teaches a disk substrate with patterned magnetic regions that are raised above the surface substrate. (see col. 2, lines 36-37; fig. 1). Regarding the limitation in claim 1 that the magnetic regions produce a plurality of localized magnetic fields when magnetized and the localized magnetic field are sufficient to trap a magnetic particle with trapping energy of at least five times greater than the thermal energy of the particle at room temperature,these are functional limitations, and the substrate of Baglin is the same as the substrate of claim 1 and thus would function like the claimed device. Claims 2-6 are rejected because they depend from these functional limitations. The magnetic regions have walls that are perpendicular to the substrate (see fig. 1). The magnetic material regions are arranged in a patterned of mutually perpendicular rows and columns. (see fig. 1). The magnetic regions comprise a layer of magnetic material (magnetic layer 24 of fig. 4) and a layer of non-magnetic material (ref. 22 of fig. 4) wherein the layer of non-magnetic material is located between the substrate (ref. 20 of fig. 4) and the layer of magnetic material (see fig. 4).The magnetic regions are uniform in shape and size. The magnetic regions have a circular cross-section. (see fig. 1). The elevated features of magnetic regions are 1 um in diameter at the base and 1 um apart. The spacing is varied from 1 to 10 um. The substrate is silicon which is non-magnetic (see co. 3, line 63-col. 4, line 9). Regarding claims 22, 23, 26, 39-41 wherein the magnetic particles are further limited, these claims are rejected because they depend

from the functional limitations of claim 1. Regarding claim 38, wherein the magnetic regions are formed by photolithography, which is a product by process claim. Thus, no patentable weight is given to the process limitations because regardless how the magnetic particles are made, the structure of the magnetic region is not altered by the device as claimed.

Claims 1-6, 10-12, 14, 15, 21-23, 26, 33, 34, 35, 38-41, 45, 46, 49, 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Gombinsky et al. (US 5,395,498).

Gombinsky teaches a magnetic particle matrix (support layer) which can be formed on a planar substrate which can be a sheet capable of adsorbing the particles, such as a nitrocellulose sheet, pergameneous sheet, cellulose acetate sheet, zerographic paper. The matrix can be prepared on a rigid substance such as a glass, a flat iron plate or an inert plastic substance, in which case the particles can be immobilized onto said rigid substance by means of a magnet attached at its other side. The (see 3, lines 54-62). The particles are evenly distributed in the matrix or non-uniformly distributed, for examples concentrated in specific locations of the matrix. Magnets arranged in a desired pattern (magnetic layer) can be used to immobilize magnetic particles to the matrix. The molecules are DNA, antibodies etc. (see 7, lines 35-40). The matrix can be incorporated into a gel (modified with a polymer). The magnetic particles having a diameter in the range of 100 to 1500nm. (see col. 7, lines 40-45). The pattern of spots in the array is simple rows of lines. (see fig. 2a). The magnetic particles have a core made of a magnetic substance such as ferrous oxide and optionally having a coating which

confer the particles binding specificity. Suitable particles have affinity to a different specific species of biological macromolecules. (see col. 7, lines 50-55). Regarding the limitation in claim 1 that the magnetic regions produce a plurality of localized magnetic fields when magnetized and the localized magnetic field are sufficient to trap a magnetic particle with trapping energy of at least five times greater than the thermal energy of the particle at room temperature,these are functional limitations, and the substrate of Gombinsky is the same as the substrate of claim 1 and thus would function like the claimed device. Claims 2-6 are rejected because they depend from these functional limitations. Regarding claims 22, 23, 26, 39-41 wherein the magnetic particles are further limited, these claims are rejected because they depend from the functional limitations of claim 1. Regarding claim 38, wherein the magnetic regions are formed by photolithography, which is a product by process claim. Thus, no patentable weight is given to the process limitations because regardless how the magnetic particles are made, the structure of the magnetic region is not altered by the device as claimed.

Claims 1-13, 15, 22, 23, 26, 30-36, 38-41, 45-57, 59-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhou et al. (US 6,355,491).

Zhou teaches electromagnetic chips and electromagnetic biochips having arrays of individually addressable micro-electromagnetic unit chip with ligand molecules immobilized on its surface. By controlling the magnetic field at teach unit of the array and combining with magnetic modification of molecules, these chips can be used for directed manipulation, synthesis and release of biomolecules in order to increase sensitivity of biochemical or chemical analysis and reduce assay time. The chip

comprises a plurality of micro-electromagnetic units (magnetic regions) fabricated on a substrate, which can be made of silicon, glass, silicon-oxide, plastics, ceramics or other solid or porous materials. The magnetic regions project above the surface of the substrate and have walls that are substantially perpendicular to the substrate (see fig. 1). Each electromagnetic unit is capable of inducing magnetic field upon circulation of an electric current about the unit and can be selectively energized through a number of means. The ligand molecules are linked to magnetic beads and together are immobilized on the biochip by the magnetic field generated by energized magnetic units which exert magnetic forces on the magnetic beads and bring the overall molecular assembly into contact with the surface of the biochip above the energized electromagnetic unit. (see col. 17, lines 5-62; figure 1; col. 18, lines 6-51). The different molecules can be DNA, biological receptors. (see col. 7, lines 54-61; col. 19, lines 15-40). The chip has a thin binding layer (functional layer) that covers the second insulation layer and is used to immobilize ligand molecules thereon; The functional layer may be formed by direct chemical modification (see col. 7, lines 1-24). The magnetic layer comprises of a sheet of plastic material impregnated with a ferromagnetic material (see col. 9, line 65-col. 10, line 13). There is a first layer of conductive traces on the substrate running between the columns of ferromagnetic cores; a first insulation layer of conductive traces on the surface of the first insulation running between the rows of ferromagnetic cores, perpendicular to the first conductive traces; a second insulation layer on the chip surface that covers the ferromagnetic core array and the second layer of conductive traces (see col. 6, lines 40-52). The superparamagnetic/ paramagnetic

microbeads may range in size from less than 100 nm to more than 100 um. These magnetic particles are uniform in size and shape and are trapped by the localized magnetic fields and comprise a detectable moiety such as a fluorescent, luminescent, nucleic acid, hybridization tag, and have a probe attached thereto. (see col. 19, lines 15-65). The pattern of magnetic regions in the array is organized rows and columns (see fig. 1). The magnetic regions are arranged in an array of subarrays configurations; and are uniform in shape and size, rectangular shape. (fig. 1). Regarding the limitation in claim 1 that the magnetic regions produce a plurality of localized magnetic fields when magnetized and the localized magnetic field are sufficient to trap a magnetic particle with trapping energy of at least five times greater than the thermal energy of the particle at room temperature,these are functional limitations, and the substrate of Zhou is the same as the substrate of claim 1 and thus would function like the claimed device. Claims 2-6 are rejected because they depend from these functional limitations. Regarding claims 22, 23, 26, 39-41 wherein the magnetic particles are further limited, these claims are rejected because they depend from the functional limitations of claim 1. Regarding claim 38, wherein the magnetic regions are formed by photolithography, which is a product by process claim. Thus, no patentable weight is given to the process limitations because regardless how the magnetic particles are made, the structure of the magnetic region is not altered by the device as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al. (US 6,355,491).

Zhou has been discussed above.

However, Zhou fails to teach the number of magnetic regions is at least 1000, 10,000, 100,000, 250, 000, or 1,000,000 per centimeter squared.

It would have been obvious to one of ordinary skills in the art to arrive at a device with that many magnetic regions based on the device of Zhou through routine experimentation for optimizing the number of magnetic particles that can be bound to those magnetic regions.

### *Allowable Subject Matter*

Claims 24, 25, 37, 42-44 are free of prior arts.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
April 28, 2005

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641
5/6/05